IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC, Plaintiffs, vs. APOTEX INC. and APOTEX CORP., Defendants.	)	C.A. No. 07-792 (GMS) (MPT)

PLAINTIFFS' OPENING BRIEF IN SUPPORT OF ITS MOTION TO ENJOIN THE PARTIES FROM PROSECUTING SECOND FILED, DUPLICATIVE LITIGATION

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INTRODUCTION

This is the first-filed forum for sanofi-aventis's and sanofi-aventis U.S. LLC's (collectively "sanofi-aventis'") claims against Defendants Apotex Corp. and Apotex Inc. (collectively "Apotex") and 13 other defendants. To protect its right to a 30-month stay of generic approval because Apotex refused to timely consent to this Court's jurisdiction, sanofi-aventis filed a second, identical action in the Southern District of Florida ("the Florida action"). Once the duplicative Florida action was filed, Apotex immediately consented to personal jurisdiction in this first-filed action, but has refused to dismiss or stay the Florida action. Sanofi-aventis moves this Court to enjoin both parties from prosecuting the second-filed, duplicative Florida action. This is sanofi-aventis's opening brief in support of that motion.

NATURE AND STAGE OF THE PROCEEDINGS

Sanofi-aventis filed this action against Apotex under the Hatch-Waxman Act for the infringement of a patent covering the drug Uroxatral® by the filing of an Abbreviated New Drug Application ("ANDA") seeking FDA approval of a generic version of that drug. Sanofi-aventis has filed two related actions in this District against 13 other defendants for patent infringement based on their ANDA filings for generic versions of Uroxatral®. The pleadings stage of all three litigations was completed in early January and a status teleconference has been scheduled for March 17, 2008.

Under the Hatch-Waxman Act, a patentee has a "strict statutory 45-day window" in which to file an infringement action after receiving notice that an ANDA has been filed in order to receive a 30-month stay of generic approval under the Act. It is unclear whether a patentee is entitled to the 30-month stay if its suit is later dismissed for lack of personal jurisdiction. Here, Apotex refused to consent to personal jurisdiction in this District within the 45-day window. Given the uncertain consequences under the Act if Apotex successfully

challenged jurisdiction in Delaware, sanofi-aventis had no choice but to file a "protective suit" in Florida where it was confident Apotex would not contest personal jurisdiction. Thus, sanofi-aventis filed a second, identical action against Apotex in the Southern District of Florida, Case No. 07-61800-CIV-MORENO/SIMONTON. That action involves exactly the same parties, claims, defenses, and counterclaims as this action. The pleading stage of that action was completed in mid-January.

Since the Florida action was filed, Apotex has consented to personal jurisdiction in Delaware. Consequently, sanofi-aventis has moved to transfer the second-filed Florida action to this District or to stay the action pending this Court's resolution of any venue issues. Briefing on sanofi-aventis's motion is complete and the parties await an order from the Florida court. Sanofi-aventis has also moved the Judicial Panel on Multidistrict Litigation ("the Panel") to transfer the Florida action to this District for consolidated pretrial proceedings with the three Uroxatral® actions pending here; the briefing on this motion was completed on March 3. Apotex has moved to transfer this case to Florida.

SUMMARY OF THE ARGUMENT

This is the first-filed forum for sanofi-aventis's claims against Apotex and the 13 other ANDA defendants. Sanofi-aventis only filed the second action in Florida to protect its right to a 30-month stay of generic approval because Apotex refused to timely consent to this Court's jurisdiction. Both this action and the Florida action involve the same parties, the same accused product, the same patent and the same issues. Rather than proceeding in Delaware where actions are currently pending against all accused infringers, Apotex seeks to squander judicial resources, game the system and engage in forum-shopping by insisting on prosecuting the Florida action in parallel. It is well-settled that this Court has a duty to enjoin the prosecution

of a second-filed action between the same parties which raises the same issues, absent rare or extraordinary circumstances. There are no such circumstances here. Consequently, this Court should enjoin both parties from prosecuting the second-filed Florida action.

STATEMENT OF FACTS

I. The Parties

Plaintiff sanofi-aventis is one of the world's leading innovators in the research, development and marketing of drugs and vaccines. It is a French corporation with places of business throughout the world, including its principal place of business in Paris, France. *See* D.I. 1 ¶ 1. Plaintiff sanofi-aventis U.S. LLC is sanofi-aventis's United States affiliate. It is a Delaware Limited Liability Company with its North American headquarters in New Jersey. *See id.* ¶ 2.

Defendant Apotex Inc. is a Canadian Company, with a place of business in Toronto, Ontario, Canada. *See* D.I. 7 ¶ 3. Defendant Apotex Corp. is a Delaware Corporation, and has places of business in a number of states, including Florida, New York and Indiana. *See id.* ¶ 4. Apotex Inc. and Apotex Corp. sell generic drugs throughout the United States, including Delaware; according to Apotex Inc.'s website, "worldwide sales of the Apotex Group of companies exceed $1 billion (Canadian $) per year." Ex. A, The Apotex Group Corporate Info.[1]

II. Sanofi-aventis's Patents And Innovator Drug

Plaintiff sanofi-aventis is the current assignee of United States Patent No. 4,661,491 ("the '491 patent"), titled "Alfuzosine Compositions and Use." D.I. 1 ¶ 11. It is also

[1] True and accurate copies of the exhibits cited herein are attached to the accompanying Declaration of Kathryn M. Liberatore in Support of Plaintiffs' Opening Brief In Support Of Its Motion To Enjoin Second Filed, Duplicative Litigation.

a current assignee of United States Patent No. 6,149,940 ("the '940 patent," issued November 21, 2000), titled "Tablet with Controlled Release of Alfuzosine Chlorhydrate."[2] D.I. 8 ¶ 12. Both patents are listed in the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral® brand alfuzosin hydrochloride 10 mg extended release tablets, the innovator drug for which Plaintiff sanofi-aventis U.S. LLC holds New Drug Application ("NDA") No. 21-287. D.I. 1 ¶ 11; D.I. 8 ¶ 13.

III. Infringement Of Sanofi-aventis's Patents By The ANDA Filers

In the Summer of 2007, nine separate ANDAs for generic versions of Uroxatral® were submitted by, on behalf of, or with participation from 15 entities, to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), including ANDA 79-013 filed by Apotex Inc. with the participation or contribution of Apotex Corp. Each of these ANDAs seeks FDA approval for the commercial manufacture, use and sale of the ANDA filer's proposed generic product prior to the expiration of one or both of sanofi-aventis's patents. As part of each ANDA, the ANDA filers included "paragraph IV certifications," alleging that the claims of the '491 patent or the '940 patent are invalid and/or not infringed by the manufacture, use or sale of the proposed generic products. Sanofi-aventis received notification of the ANDAs and paragraph IV certifications in letters dated between August 14, 2007 and October 25, 2007, including notification of Apotex's ANDA and '940 patent paragraph IV certification by letter dated August 14, 2007 and notification that Apotex amended its ANDA to include a '491 patent paragraph IV certification by letter dated October 25, 2007. Ex. B, 08/14/07 B. Sherman ltr to Plaintiffs and Jagotec AG; Ex. C, 10/25/07 B. Sherman ltr to Plaintiffs and Jagotec AG.

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2 Non-party Jagotec AG is also a current assignee of the '940 patent. Plaintiff sanofi-aventis has an exclusive license to Jagotec AG's interests in the '940 patent. D.I. 8 ¶ 12.

The submission of these ANDAs and paragraph IV certifications permitted sanofi-aventis to sue for infringement of the '491 patent and/or the '940 patent. *See* 35 U.S.C. § 271(e)(2)(A). To litigate this infringement under the protections provided by the Hatch-Waxman Act, which affords a 30-month stay of generic approval while a patent litigation is pending, sanofi-aventis was required to file an action against each submitting party or parties within forty-five days of receiving notice of their respective paragraph IV certifications. 21 U.S.C. § 355(j)(5)(B)(iii).

IV. Commencement Of The First-Filed District Of Delaware Actions

A. Plaintiffs Initially Sued 13 Defendants For Infringement of the '491 and/or '940 Patents In This District

After receiving notice of the ANDAs and paragraph IV certifications, sanofi-aventis evaluated various personal jurisdiction issues and determined that the most logical venue for litigating its claims against all 15 potential defendants, including Apotex, was the District of Delaware. In light of this fact and the judicial economy and efficiency of having the same court try sanofi-aventis's claims against every defendant, sanofi-aventis commenced Civil Actions Nos. 07-572 (GMS) (MPT) and 07-574 (GMS) (MPT) on September 21, 2007 in this District against 13 defendants for infringement of the '491 and/or the '940 patent by the filing of their respective paragraph IV certifications.[3] *See* Ex. D, Delaware Complaint No. 07-572; Ex. E, Delaware Complaint No. 07-574.

[3] In these two actions, sanofi-aventis asserted both patents against nine defendants and the '940 patent alone against four additional defendants.

B. Plaintiffs Sued Apotex For Infringement Of The '491 Patent In This District Shortly Thereafter

At the time of filing the first two Delaware complaints, Apotex's ANDA only included a paragraph IV certification against the '940 patent. *See* Ex. B. In reliance on Apotex's representations regarding its proposed generic product, sanofi-aventis informed Apotex that it would not file an action for infringement of the '940 patent unless Apotex's representations were incorrect or Apotex amended its ANDA to change the composition of its proposed generic product. Ex. F, 10/01/07 W. Vuk ltr to B. Tao. Sanofi-aventis then received a second paragraph IV certification from Apotex dated October 25, 2007, alleging that its proposed generic product did not infringe any valid claim of the '491 patent. Ex. C. In response, sanofi-aventis commenced Civil Action No. 07-792 (GMS) (MPT) against Apotex for infringement of the '491 patent in this District on December 6, 2007. D.I. 1. That action was designated as related to the earlier-filed complaints and assigned to the same Judge and Magistrate Judge.

C. Apotex Agreed Not To Contest Jurisdiction In Delaware Only After The Expiration Of Plaintiffs' 45-Day Window To Bring Suit

Despite having previously admitted personal jurisdiction in several prior actions in this forum,[4] Apotex ignored sanofi-aventis's request to consent to jurisdiction prior to the expiration of the 45-day window to bring suit under the Hatch-Waxman Act. *See* Ex. H,

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[4] On at least four separate occasions with respect to other ANDA litigations, Apotex has admitted that the District of Delaware has jurisdiction over it. Ex. G, Answer in *Allergan, Inc. v. Apotex Inc. et al*, Civ. No. 07-278-GMS at 2-3; Answer in *Medpointe Healthcare Inc. v. Apotex Inc.* et al. No. Civ. 07-204-SLR at 3**;** Answer in *Medpointe Healthcare Inc. v. Apotex Inc. et al.*, No. Civ. 06-164-SLR at 3-4; Answer in *Merck & Co., Inc. v. Apotex Inc.*, No. Civ. 06-230-GMS at 2. In fact, Apotex has also availed itself of the Delaware court as a plaintiff. Ex. G, Complaint in *Torpharm Inc. et al. v. Pfizer Inc. et al.*, No. Civ. 03-990-SLR at 4**.**

12/06/07 W. Vuk ltr to B. Sherman and T. McIntyre. It was only after the 45 days had run that Apotex stated that it would not contest jurisdiction in Delaware. Ex. I, 12/11/07 M. Noreika email to S. Rollo; Ex. J, 12/31/07 M. Noreika ltr to S. Rollo. On January 2, 2008, Apotex answered the Delaware complaint and conceded that jurisdiction and venue were proper in this forum:

- "Apotex Corp. admits that [the Delaware] Court has personal jurisdiction over it in this District for the purposes of this action." D.I. 7 ¶ 7;
- "For purposes of this action, Apotex Inc. does not contest the [Delaware] Court's jurisdiction over it . . . ." *Id.* ¶ 8;
- "Apotex Inc. and Apotex Corp. do not dispute this judicial district is a possible venue for this action . . . . " *Id.* ¶ 10.

Nevertheless, Apotex indicated that it would move to transfer the first-filed Delaware action to the Southern District of Florida because that is "a more convenient venue" and "will proceed more quickly to resolution." *See* D.I. 7 ¶ 10; Ex. K, 01/07/08 S. Feldman ltr to W. Vuk; Ex. L, 01/07/08 W. Vuk ltr to S. Feldman.

All three earlier-filed Delaware actions are designated as related cases and all are proceeding before the same Judge and Magistrate Judge. As of January 7, 2008, all 15 defendants, including Apotex, had filed their answers and counterclaims and sanofi-aventis had filed all of its replies. The Court in this action will hold a status teleconference on March 17, 2008 and all the parties are currently engaged in discussions to negotiate a global protective order. Ex. M, 02/28/08 J. Parrett email to P. Molino, et al.

V. Plaintiffs Brought The Second-Filed Florida Action To Protect Their Rights Under The Hatch-Waxman Regime In Response To Apotex's Failure To Confirm That It Would Not Contest Jurisdiction In Delaware

Apotex's refusal to consent to jurisdiction in this District within the 45-day window to bring suit placed sanofi-aventis in a significant dilemma. Under the Hatch-Waxman Act, a patentee has a "strict statutory 45-day window" in which to file an infringement action

after receiving notice that an ANDA has been filed seeking approval to market a generic version of a patented drug product. *Abbott Labs. v. Mylan Pharm., Inc.*, No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006) (citing 21 U.S.C. § 355 (j)(5)(B)(iii)). Sanofi-aventis met this deadline with respect to 13 defendants by its September 21, 2007 complaints in this Court and with respect to Apotex by its December 6, 2007 Complaint in this Court. But it is unclear whether a patentee still enjoys the benefits of a suit under the Hatch-Waxman Act (as opposed to a suit for infringement generally under the patent laws) if its action, properly brought within the 45-day window, is dismissed for lack of personal jurisdiction after the 45-day period has expired. *See, e.g., PDL BioPharma, Inc. v. Sun Pharm. Indus., Ltd.*, No. 07-11709, 2007 WL 2261386, at *2 (E.D. Mich. Aug. 6, 2007); *Abbott*, 2006 WL 850916, at *8.

Although sanofi-aventis believed that this Court could properly exercise personal jurisdiction over Apotex, the Southern District of Florida was the only district in which sanofi-aventis knew Apotex would not contest personal jurisdiction based on prior litigation conduct and representations made in Apotex's certification letters. *See* Exs. B, C. Given the uncertain consequences surrounding the unlikely, but possible dismissal of the Delaware action, sanofi-aventis had no choice but to bring the second-filed Florida action within the 45-day window on

December 10, 2007.[5] Ex. O, Florida Complaint. Plaintiffs made their intention in filing the second suit entirely clear in the complaint itself:

> Plaintiffs have sought to enjoin Defendant Apotex Inc.'s and Defendant Apotex Corp.'s infringing activities in an action filed by Plaintiffs in the District of Delaware on December 7, 2007, Civil Action No. 07-792 and will seek to have that action coordinated or consolidated with an action brought to enjoin acts of infringement of the '491 patent by numerous defendants filed by Plaintiffs in the District of Delaware on September 21, 2007, Civil Action No. 07-572 GMS (MPT). Defendant Apotex Inc. and Defendant Apotex Corp. are properly subject to personal jurisdiction in the District of Delaware and judicial economy would be promoted by all of Plaintiffs' claims for infringement of the '491 patent being addressed in the District of Delaware. Upon information and belief, Plaintiffs understand that Defendants may nevertheless contest jurisdiction in that venue. Given the possible consequences if Defendants succeeded with such unjustified action, Plaintiffs had no choice but to file this Complaint. In the event that Defendants are unsuccessful in any such challenge, Plaintiffs will dismiss this action.

Ex. O ¶ 19 (emphasis added). Plaintiffs never served the Florida complaint on Apotex. As discussed above, Apotex subsequently agreed not to contest jurisdiction in Delaware, but would not confirm that agreement in writing before answering in Florida so that sanofi-aventis could voluntarily dismiss that complaint. Plaintiffs have since moved to transfer the Florida action to

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[5] The consequences of losing the protections of the Hatch-Waxman Act are significant to the parties and the courts. Under the Act, approval of the proposed generic product is stayed by the FDA for 30 months and the action can be litigated in an orderly fashion without any damages issues or questions of emergency injunctions. 21 U.S.C. § 355(j)(5)(B)(iii); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 344 (D.N.J. 2003) ("The purpose of the 30-month stay is to allow time for patent infringement litigation."); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001). Absent these protections, cases can devolve into free-for-alls with generic defendants seeking to launch "at-risk" and patentee plaintiffs seeking temporary restraining orders, preliminary injunctions and significant damages.

this District, or in the alternative, to stay the Florida action pending the resolution of the venue dispute by this Court. Ex. P, Plaintiff's Florida Motion To Transfer Or Stay.[6]

It is now clear that Apotex sought to make an end run around Plaintiffs' choice of this forum. Apotex filed its Answer and Counterclaims in the Florida action on December 28, 2007, one business day before answering the first-filed Delaware complaint.[7] *See* Ex. R, Florida Answer And Counterclaims; Ex. S, Florida Amended Answer And Counterclaims. It appears that Apotex's strategy was to ignore sanofi-aventis's inquiry as to whether it would contest jurisdiction in Delaware, in an effort to force sanofi-aventis to file a protective action in Apotex's forum of choice. Apotex now seeks to buttress its argument that Florida is "more convenient" with the "fact" that the Florida action has progressed farther than the Delaware actions, arguing that the Florida action is well underway because the parties have exchanged initial disclosures and Apotex has served document requests and interrogatories. Ex. T, Defendants Apotex Inc.'s and Apotex Corp.'s Rule 26(a)(1) Initial Disclosures; Ex. U, 01/17/08 W. Vuk ltr to S. Feldman and S. Bronis; Ex. V, Plaintiffs' Initial Disclosures Pursuant to Rule 26(a)(1); Ex. W, Defendants Apotex Inc.'s and Apotex Corp.'s First Request For The Production Of Documents And Things To Plaintiffs; Ex. X, Defendants Apotex Inc.'s and Apotex Corp.'s First Interrogatories To Plaintiff. Sanofi-aventis has responded to Apotex's document requests, but has objected to

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6 Plaintiffs have also moved the Panel to transfer the Florida action to this District for consolidated pretrial proceedings with the three Uroxatral® actions pending here. *See* Ex. Q, Plaintiffs' Motion To Transfer And Consolidate For Pretrial Proceedings. Apotex has moved to transfer this case to Florida. D.I. 10.

7 In its Florida answer, Apotex "den[ies] that Apotex Inc. is subject to personal jurisdiction in the Delaware action . . . ." Ex. Q ¶ 19. Apotex then contradicted that denial in its Delaware Answer, stating that it does not contest this Court's personal jurisdiction over Apotex Inc. D.I. 7 ¶ 8; *see also* Ex. I; Ex. J.

producing any documents pending the resolution of the outstanding motions. Ex. Y, Plaintiffs' Objections and Response to Defendants' Document Requests. Notably, Apotex has failed to identify a single witness or document located in the Southern District of Florida. Ex. T. Moreover, the Florida court has not held its initial case management conference. As discussed below, this District, the Third Circuit and courts throughout the country have rejected attempts by defendants to game the system by enjoining the prosecuting of second-filed actions—like the Florida action—because such later-filed actions allow defendants to secure the forum of their choice at the expense of wasting court resources, duplicating pretrial activities, unduly burdening the parties and witnesses, and risking inconsistent rulings.

ARGUMENT

The Court should apply the first-filed rule and enjoin both sanofi-aventis and Apotex from prosecuting the second-filed Florida action. Without enjoining further activities in Florida, the courts and the parties will engage in duplicative pretrial activities, thereby wasting resources, unduly burdening the parties and witnesses, and risking inconsistent rulings. Apotex will likely argue that the first-filed rule should not apply here because sanofi-aventis filed both the Delaware and Florida actions. This argument, however, is directly contradicted by the case law, which applies the first-filed rule even where both actions are initiated by plaintiffs and recognizes the need for protective suits in ANDA actions due to the jurisdictional ambiguities concerning the Hatch-Waxman Act. Finally, there are no extraordinary circumstances that would lead to a deviation from the first-filed rule in this case.

I. This Court Has The Duty To Enjoin Both Parties From Prosecuting The Second-Filed Florida Action

There is no legitimate basis for requiring a party to prosecute the same lawsuit in two different courts. It is an utter waste of scarce judicial resources, requiring two judges to do

the same work in parallel and it wastes the parties' resources by necessitating duplicative discovery and other pretrial proceedings, as well as causing great inconvenience to the parties and witnesses. Allowing the same lawsuit to be prosecuted in two different courts also risks potentially inconsistent rulings on issues that impact the certainty of patent rights. For these reasons, courts follow the "first-filed" rule which provides that the first-filed action should proceed and the parties should be enjoined from prosecuting a second-filed action.

The first-filed rule originated with the United States Supreme Court in *Smith v. Mclver*, 22 U.S. (9 Wheat.) 532 (1824). In *Smith*, Chief Justice Marshall ruled that "in all cases of concurrent jurisdiction, the court which first has possession of the subject must decide it." *Id.* at 535. Over sixty years ago, the Court of Appeals for the Third Circuit applied this principle to federal concurrent jurisdiction in *Crosley Corp. v. Hazeltine Corp.*, 122 F.2d 925 (3d Cir. 1941), *cert. denied*, 315 U.S. 813 (1942). The Third Circuit held that the district court had abused its discretion in failing to enjoin the parties from prosecuting a second-filed action, explaining that:

> [i]t is of obvious importance to all the litigants to have a single determination of their controversy, rather than several decisions which if they conflict may require separate appeals to different circuit courts of appeals. . . . The party who first brings a controversy into a court of competent jurisdiction for adjudication should, so far as our dual system permits, be free from the vexation of subsequent litigation over the same subject matter.

Id. at 930. The Third Circuit also noted that:

> [t]he economic waste involved in duplicating litigation is obvious. Equally important is its adverse affect upon the prompt and efficient administration of justice. . . . Courts already heavily burdened with litigation with which they must of necessity deal should therefore not be called upon to duplicate each other's work in cases involving the same issues and the same parties.

Id. at 930; *see also Crosley Corp. v. Westinghouse Elec. & Mfg. Co.*, 130 F.2d 474, 475 (3d Cir. 1942), *cert. denied*, 317 U.S. 681 (1942) ("[T]he district court first obtaining jurisdiction of the parties and issues in a patent cause on a complaint seeking declaratory relief should ordinarily proceed to adjudicate the controversy and should restrain the parties from seeking in the interim in a later suit in another district court to duplicate that adjudication").

Courts not only have the power to enjoin parties from prosecuting second-filed actions, but the case law makes clear that courts have the duty to enjoin the parties from prosecuting a second-filed action where the parties, patents, and issues are the same. In *Triangle Conduit & Cable Co., Inc. v. National Electric Products Corp.*, 125 F.2d 1008, 1009 (3d Cir. 1942), *cert. denied*, 316 U.S. 676 (1942), the Third Circuit explained this duty:

> "***it was the duty of the Court first obtaining jurisdiction to enjoin the prosecution of the subsequent proceedings in the other court***. As we have seen, in the present case the district court in Delaware first obtained jurisdiction of Triangle and National and of the controversy between them. Having taken jurisdiction of the declaratory suit brought by Triangle, it became the duty of that court to adjudicate the controversy."

Id. at 1009 (emphasis added).

The Court of Appeals for the Federal Circuit likewise has adopted the "first-filed" doctrine. In *Laboratory Corp. of America Holdings v. Chiron Corp.*, the Federal Circuit affirmed a District of Delaware order enjoining the prosecution of a second-filed California action in favor of a first-filed Delaware action. 384 F.3d 1326, 1332-33 (Fed. Cir. 2004); *see also Genentech Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 937 (Fed. Cir. 1993), *cert. denied*, 510 U.S. 1140 (1994), *overruled in part on other grounds by Wilton v. Seven Falls Co.*, 515 U.S. 277, 289 (1995) ("The general rule favors the forum of the first-filed action, whether or not it is a

declaratory action."); *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 935 F.2d 1263 (Fed. Cir. 1991) (affirming injunction by a Texas district court barring prosecution of second-filed action).

Following these authorities, this Court has repeatedly enjoined the prosecution of second-filed actions, and should not hesitate to do so in this action. *See, e.g., Cosden Oil & Chem. Co. v. Foster Grant Co., Inc.*, 432 F. Supp. 956, 960 (D. Del. 1977), *aff'd w/o op.*, 577 F.2d 725 (3d Cir. 1978) (citations omitted) (A plaintiff in this Court is "entitled to be free from the 'vexation of subsequent litigation over the same subject matter' . . . and the courts are entitled to be free from the waste and inefficiency involved in duplicative litigation."); *Rohm & Haas Co. v. Brotech Corp.*, 770 F. Supp. 928 (D. Del. 1991); *Bamdad Mechanic Co., Ltd. v. United Tech. Corp.*, 109 F.R.D. 128 (D. Del. 1985). *Cf. Celgene Corp. v. Abrika Pharm., Inc.*, Civ. No. 06-741-SLR, slip op. at 1 (D. Del. Jul. 18, 2007) (Judge Robinson dismissed the second-filed action as she was "not persuaded that the facts of this case warrant an exception to the 'first filed rule.'");[8] *Celgene Corp. v. Abrika Pharm., Inc.*, No. 06-5818, 2007 WL 1456156, at *4 (D.N.J. May 17, 2007) (recognizing plaintiffs' choice of forum and the first-filed rule, the court declined to transfer the first-filed New Jersey action to Delaware where "Plaintiffs had a legitimate reason to file a similar, even identical action in Delaware, in order to ensure that they would not be time-barred from bringing the action at all should this Court find that it did not have personal jurisdiction over Defendants."); *Airport Investors Ltd. P'ship, Inc. v. Neatrour*, No. 03-831 GMS, 2004 WL 225060, at *2 (D. Del. Feb. 3, 2004) (recognizing that, although not addressed by the parties, "the 'first-filed' rule of this Circuit likely dictates" transfer of the second-filed

[8] Ex. Z is a compendium of unreported cases cited herein.

Delaware action to the first-filed forum even though plaintiffs brought both actions against defendants).

II. This Court Has Enjoined Parties From Prosecuting Second-Filed Actions When Both Actions Have Been Brought By The Same Party

Apotex will likely argue that the first-filed rule does not apply because sanofi-aventis filed both the initial action and the second action.[9] This argument is directly contradicted by the precedent of this Court and various district courts around the country; these courts have not only applied the first-filed rule where plaintiffs have brought both actions, but also have explicitly recognized the need for protective suits, such as the Florida action, in ANDA cases.

For example, in *Bamdad Mechanics Co. v. United Technologies Corp.*, this Court reasoned that even though "[t]he *Westinghouse* and *Hazeltine* decisions deal with the more common situation in which the defendant in the first action files suit in another forum against the original plaintiff[,] [t]he same rules applies, however, where two suits are initiated by the same plaintiff." 109 F.R.D. at 132 (enjoining plaintiffs, who "candidly admit to a degree of forum-shopping," from litigating a second-filed action in Connecticut in favor of the first-filed action in Delaware).

Likewise, in *Old Charter Distillery Co. v. Continental Distilling Corp.*, the plaintiff filed a first action in the District of Columbia ("the DC action") and the second action in the District of Delaware "***as a precautionary step*** in case the United States District Court or the

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9 In its motion to transfer this action to the Southern District of Florida, or in the alternative, to stay this case pending final resolution of that action, Apotex argued against the application of the first-filed rule where plaintiff has filed both actions. *See* D.I. 11 at 11, 13. Plaintiffs' answering brief in opposition to Apotex's motion includes a discussion of why the first-filed rule should apply. *See* D.I. 14 at 12-17.

Circuit Court of Appeals of the District of Columbia or the Supreme Court decided there was no jurisdiction over defendant" in the DC action. 59 F. Supp. 528, 530 (D. Del. 1945) (emphasis added). Plaintiffs requested an injunction preventing the parties from prosecuting the first-filed DC action, but this Court refused to grant such an injunction because "the District Court in the [DC] action has ruled that it has jurisdiction over defendant and the subject matter of the controversy between the parties. It is the court first acquiring jurisdiction and it is entitled to maintain that jurisdiction until it makes final adjudication of the matters for determination. In fact that court has power to enjoin defendant from prosecuting its present motion for preliminary injunction or proceeding with its counterclaim in this [Delaware] court." *Id.* at 530 (internal citations omitted). This Court went on to hold:

> Defendant's contention that this court is the court of greatest convenience for the parties has been examined and carefully considered. But there is nothing to be gained by elaborating this point. Plaintiff, by commencing the [DC] action, has selected what it considers to be the proper forum for the protection of its property right. The exercise of such selection should not, it seems to us, be subordinated by the application of the doctrine of forum non conveniens in favor of defendant under the circumstances presented here. It is appropriate that a stay of the case at bar should be granted, with the right reserved to each of the parties to make a renewal of their present motions or to file additional applications in the event the complexion of the litigation in the United States District Court for the District of Columbia changes in any material respect.

Id. at 531.

Moreover, courts, including this District and others in the Third Circuit, have applied the first-filed rule in ANDA cases where plaintiffs brought both actions and have expressly recognized the need for second-filed "protective suits" in ANDA litigations due to the ambiguities concerning jurisdictional challenges under the Hatch-Waxman Act and the serious risks patentees face if their first-filed actions are dismissed—namely the loss of the 30-month

stay of generic approval while a patent litigation is pending. *See e.g.*, *Celgene Corp. v. Abrika Pharms., Inc.*, Civ. No. 06-741-SLR, slip op. at 1 (D. Del. Jul. 18, 2007) (dismissing second-filed protective suit because the court was "not persuaded that the facts of this case warrant an exception to the 'first filed rule.'"); *Celgene Corp. v. Abrika Pharms., Inc.*, No. 06-5818, 2007 WL 1456156, at *1, 4 (D.N.J. May 17, 2007) (denying motion to transfer first-filed action where "Plaintiffs had a legitimate reason to file a similar, even identical action [as a protective suit] in [the second-filed forum], in order to ensure that they would not be time-barred from bringing the action at all should this Court find that it did not have personal jurisdiction over Defendants."); Ex. AA, *Abbott Labs. v. Andrx Corp.*, Case 00-6520-CV-S, Transcript of Scheduling Conference (S.D. Fla. July 10, 2000) at 12-13 (granting limited stay of second-filed ANDA action while first-filed court decided jurisdictional issues); *PDL Biopharma, Inc. v. Sun Pharm. Ind., Ltd.*, No. 07-11709, 2007 WL 2261386, at *2 (E.D. Mich. Aug. 6, 2007) (staying second-filed ANDA action and recognizing the need for "protective" suits as a successful jurisdictional challenge in the first-filed court could preclude the patentee from bringing any suit under the Hatch-Waxman Act); *Schering Corp. v. Caraco Pharm. Labs., Ltd.*, No. 06-14386, 2007 WL 1648908, at *4 (E.D. Mich. June 6, 2007) (staying second-filed ANDA action while first-filed court, where claims against 19 other ANDA defendants were pending, decided jurisdictional issues, *inter alia*, to avoid "the probable inefficiency and the potential for the misuse of the limited resources of the judiciary"); *Aventis Pharma S.A. v. Sandoz Inc.*, No. 06-3671 (MLC), 2007 WL 1101228, at *3 (D.N.J. Apr. 10, 2007) ("Aventis's explanation that it filed a virtually identical complaint in New Jersey after filing in California 'in case Sandoz contested in personam jurisdiction in California and to preserve its rights to a 30-month stay of FDA approval of Sandoz's application' sufficiently refutes any allegation of judge or forum shopping by Sandoz."); *Abbott Labs. v.*

Mylan Pharms., Inc., No. 05 C 6561, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006); *cf. Medpointe Healthcare Inc. v. Cobalt Pharms. Inc.*, No. 07-4017 (JAP), slip op. at 3 (D.N.J. Jan. 28, 2008) (denying transfer from the first-filed forum even though plaintiff had filed both the initial ANDA patent infringement action and the second "protective" suit against the same defendant).

Here, the first-filed rule should apply because there is no question that sanofi-aventis had a legitimate need to bring the second-filed "protective suit" in Florida. Sanofi-aventis even expressly stated its motivation in the Florida complaint itself. *See* Ex. O ¶ 19. Under the Hatch-Waxman Act, a patentee has a "strict statutory 45-day window" in which to file an infringement action after receiving notice that an ANDA has been filed in order to receive a 30-month stay of generic approval under the Act.[10] It is unclear whether a patentee is entitled to the 30-month stay if its suit is later dismissed for lack of personal jurisdiction. Here, Apotex refused to consent to personal jurisdiction in this District within the 45-day window despite having previously admitted personal jurisdiction in several prior actions in the District of Delaware. Given the uncertain consequences under the Act if Apotex successfully challenged jurisdiction in Delaware, sanofi-aventis had no choice but to file a "protective suit" in Florida

[10] Before the Panel, Apotex has suggested that NDA owners should file suit within the first 24 days of the 45-day period. This position defies logic and is contrary to the purpose of the Hatch-Waxman Act in providing a 45-day period of time for innovator companies to bring suit. *See* Ex. N, Apotex's Response And Opposition To Plaintiffs' Motion For Transfer of Action Pursuant to 28 U.S.C. § 1407, at 17 ¶ 14. The purpose of the 45-day period is to provide the patentee with sufficient time to determine whether the proposed generic product infringes the patent. Congress did not provide a 45-day period so that jurisdictional challenges could be resolved. If that were the case, every generic company would wait until the end of the 45-day period to contest jurisdiction, thereby ensuring that the jurisdictional question would not be resolved until after the 45-day period ended and the patentee lost the right to the 30-month stay.

where it was confident Apotex would not contest personal jurisdiction. Thus, the first-filed doctrine is clearly applicable here.

III. There Are No Rare Or Extraordinary Circumstances Justifying Departure From The First-Filed Rule

While departure from the first-filed rule is only warranted in "rare or extraordinary circumstances," such as those involving "inequitable conduct, bad faith, or forum shopping," *EEOC v. University of Pennsylvania*, 850 F.2d 969, 972 (3d Cir. 1988), *aff'd on other grounds*, 510 U.S. 1140 (1994), there are no such circumstances here. Sanofi-aventis had a rational and legitimate reason to bring suit in Delaware because it is the district where it could bring each of the 15 ANDA filers and related defendants under the jurisdiction of one court so that all claims and counterclaims regarding Uroxatral® and the listed patents could be adjudicated in a single forum. In addition, this Court has significant expertise in handling patent matters, and has a record and policy of getting patent cases to trial promptly and efficiently.

Apotex can hardly argue that sanofi-aventis's filing of parallel actions is motivated by inequitable conduct, bad faith or forum shopping. Sanofi-aventis was forced by Apotex's initial refusal to consent to jurisdiction in Delaware and the lack of guidance in the statute and case law regarding the effect of the possible dismissal of a suit for lack of personal jurisdiction on a patentee's Hatch-Waxman rights to file a "protective action" in Florida. Such protective suits have been found to be necessary, and do not constitute forum shopping. *See PDL Biopharma, Inc.*, No. 07-11709, 2007 WL 2261386, at *2 (noting that the reasons for filing protective suit "do not demonstrate bad faith or forum shopping on the part of Plaintiff."); *Aventis Pharma*, No. 06-3671 (MLC), 2007 WL 1101228, at *4 (explaining that the necessity of protect suits sufficiently refutes any allegation of judge or forum shopping). The first-filed rule should apply to enjoin the parties from prosecuting the later-filed, duplicative Florida action in

the absence of rare or extraordinary circumstances such as inequitable conduct, bad faith, or forum shopping.

As it argued in its motion to transfer to Florida, Apotex will likely argue here that the Florida court will expedite the resolution of the parties' claims. *See* D.I. 11 at 12. To date, the Florida action has not progressed substantially beyond the progression of this case. The parties have exchanged initial disclosures, and while Apotex has served document requests and interrogatories, sanofi-aventis has responded to Apotex's document requests, but has objected to producing any documents pending the resolution of the outstanding motions. The parties have not yet had their case management conference with the court.[11] The Court in this action, however, will hold a status teleconference on March 17, 2008 and the parties are currently engaged in discussions to negotiate a global protective order. Thus, any suggestion by Apotex that the Florida case is proceeding much more expeditiously is misleading. Here, the interests of justice are best served and the resolution of Plaintiffs' claims will best be expedited when all of sanofi-aventis's claims for infringement proceed in the same forum to avoid a waste of judicial resources and prevent inconsistent rulings. Enjoining the continued prosecution of the Florida action in favor of the Delaware action will avoid duplicating pretrial activities, thus preserving judicial resources, reducing costs for the parties, and expediting the resolution of the claims for all parties' involved.

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[11] Indeed Apotex has refused sanofi-aventis's request to schedule a court conference in the Florida action and has forced sanofi-aventis to file a motion requesting a conference regarding essential issues in any patent litigation—discovery parameters and a Markman hearing. *See* Ex. BB, Plaintiff's Motion For Status Conference.

As it has argued in previous motions, Apotex will likely claim that the Florida action should proceed to further the Hatch-Waxman Act's goal of getting low-cost drugs into the hands of consumers. *See, e.g.*, Ex. CC, Defendants' Opposition to Plaintiffs' Motion To Stay Or Transfer in Florida, at 3. What Apotex fails to mention is that this is not the only goal of the Hatch-Waxman Act. Apotex further argues that the Hatch-Waxman Act requires that ANDA suits proceed to a "speedy resolution." *See, e.g.*, Ex. CC, at 9. But nothing in the Hatch-Waxman Act suggests that ANDA litigations should be tried as quickly as possible at any expense. Rather, in implementing the Act "Congress struck a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring lowcost, generic copies of those drugs to market." *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1327 (Fed. Cir. 2005). The Act recognized the importance of patentees' rights by making the filing of an ANDA and paragraph IV certification an act of infringement and by providing for a 30-month stay of FDA approval so that the infringement actions could be litigated in an orderly fashion without any damages issues or questions of emergency injunctions. 21 U.S.C. § 355(j)(5)(B)(iii); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 344 (D.N.J. 2003); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579 (D.N.J. 2001).

Requiring innovators such as sanofi-aventis to conduct duplicative litigation in multiple fora, as Apotex seeks to do, would result in increased costs to innovators, reducing their incentives to bring new drugs to market and frustrating a key purpose of the Hatch-Waxman Act. In any event, Apotex's conduct in the litigation to date demonstrates that the availability of low-cost drugs is not its concern. Apotex's gambit of aggressively pressing this case while seeking to delay the Delaware action is motivated by the potential for significant financial gain to Apotex if

it is able to enter the market with a generic copy of Uroxatral® without competition from the other defendants. In fact, the other ANDA defendants themselves agree that they would be unfairly prejudiced:

> [I]f Apotex obtains a non-infringement ruling on the '491 patent in the Florida Action prior to the other first filers obtaining a judgment in the other Related Actions, the FDA will terminate Apotex's 30-month stay, and Apotex will be able to go to market before the other first filers. ***This is contrary to the Hatch-Waxman Act, which was designed to provide the exclusivity incentive to all first filers. Any other result has the potential of improperly stripping certain first filers of the important exclusivity incentive.***

Ex. DD, Defendants Actavis South Atlantic LLC's And Par Pharmaceutical, Inc.'s Response In Support of Motion to Transfer And Consolidate, at 9 (emphasis added). Under these circumstances, allowing duplicative actions to proceed in parallel would provide Apotex with a powerful incentive to delay resolution of the Delaware action, thereby in fact reducing the potential for the generic competition that Apotex proposes to espouse.

Moreover, the parties must be enjoined from prosecuting the later-filed, duplicative Florida action to avoid potentially enormous duplication of efforts concerning depositions and other discovery. Based on the invalidity arguments presented by defendants in their paragraph IV certification letters, it appears that all are relying on the same or similar prior art references to argue that the claims of the patents-in-suit are invalid. Likewise, each of the proposed generic products is a purported once-a-day formulation referencing Plaintiffs' Uroxatral® product, including its proposed indication. Enjoining the parties from prosecuting the Florida action will allow all of the defendants to equally participate in the depositions of witnesses concerning the development of Uroxatral® and prosecution of the patents-in-suit, as well as all regulatory and marketing issues on which the defendants may seek discovery. Multiple depositions of the same witnesses on the same issues will not be necessary. Discovery

disputes that arise will be handled by a single court, avoiding duplication of efforts and potentially inconsistent rulings. Sanofi-aventis, who has the burden of collecting, reviewing, and processing hundreds of thousands if not millions of pages of documents for production, will be able to proceed with discovery under a single court's rulings. Furthermore, with an injunction, only one court will be required to learn the technology associated with the patents-in-suit, the alleged prior art, and the proposed generic products.

Finally, enjoining the parties from prosecuting the Florida action will prevent potentially inconsistent rulings on critical issues such as claim construction, the validity of the asserted claims, and, to the extent the ANDA filers allege similar defenses, whether the proposed generic products infringe those claims. Thus, enjoining the parties from prosecuting the later-filed, duplicative Florida action will serve the interests of justice for all parties.

CONCLUSION

For the foregoing reasons, sanofi-aventis requests that the Court enjoin sanofi-aventis and Apotex from prosecuting the second-filed, duplicative Florida action.

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CERTIFICATE OF SERVICE

I hereby certify that on March 4, 2008 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to:.

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I further certify that I caused to be served copies of the foregoing document on March 4, 2008 upon the following in the manner indicated:

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